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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,422	06/09/2006	Hoi-Ying N. Holman	LBNL-238 (IB-1867-US)	4848

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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
11/22/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyipdocket@fulbright.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,422	HOLMAN, HOI-YING N.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *29-30 and 32-50* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 29-30, 32, 34-39, 42-47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) stand alone or in view Helfer et al (US Pat: 5,197,470).

Regarding claims 29-30, 34, 42-43 and 50 Rava et al disclose a spectroscopic method to obtain molecular vibration information with attenuated total reflectance (ATR) of infrared light [see column 8 lines 31-34]. Rava et al disclose in figs 12A and 12B diagnostic measurements within the human body; probe 100 with one or more optical fibers 102 both the incident light to, and the transmitted (reflected) light from, the ATR element 104. A 100% infrared reflector 106 such as gold is placed at the distal surface 108 of the ATR element 104 functions to return the transmitted light back through the same fiber [see column 9 lines 11-25].

Rava et al further disclose irradiating a subsurface portion of atherosclerotic tissue within a vascular lumen to be diagnosed with radiation having a frequency within the infrared range transmitted through a fiber optic cable [see claim 1, Rava et al] and further mention the detecting step further comprises collecting the emitted light through the fiber optic cable [see claim 2] and determining chemical compositions and cellular

conditions [see column 11 lines 1-25, column 13 lines 1-20, 42-45, column 16 lines 66-67 and column 17 lines 1-10].

Rava et al disclose IR beam from FT-IR is transmitted through IR optical fiber 122 to ATR element 128 positioned at the distal end of catheter body 120. The Transmitted light is conducted through second IR optical fiber 124 back to an IR detector [see column 9 lines 33-44]. Rava et al disclose radiation is transmitted 112 and collected 114 from element 104 [see column 9 lines 20-32, figs 12A-B].

Rava et al disclose computer 215 that stores information in a memory as a spectrum which is a graph of intensity vs wavelength which can be displayed on display 82 or compared with existing spectrum stored in the computer; and further mention the comparative data is shown in a display to provide quantitative measure of the health of the tissue observed [see column 4 lines 55-68].

Rava et al further disclose comparing mid-IR of a normal tissue to atherosclerotic plaque and observe increases in several bands in the atherosclerotic regions [see column 13 lines 46-60]. Rava et al disclose mid-infrared spectra were measured from 4000 to 700 cm^-I with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67]. Since a peak about 1515 cm^-1 or 1520-1500 cm^-1 is within the range 1800 and 700 cm^-1; therefore, Rava et al disclose refractive indices from human tissue vary between 1800 and 700 cm^-1 [see column 14 lines 17-18] which means at peak of about 1515 cm^-1 can be used to diagnose human tissue.

Rava et al disclose the probe can either be inserted through a standard endoscope or catheter to sample a hollow organ (or artery) [see column 9 lines 20-32] which is a blood vessel.

In the alternative, Heifer et al disclose optical means for transmitting and receiving light energy from the fibers to a blood vessel and from the illuminated blood vessel to the fibers, respectively; means for delivering the generated energy to the at least one fiber, means for detecting the amount of such generated energy that is not absorbed by illuminated tissue in a blood vessel and means for discriminating illuminated healthy tissue from illuminated diseased tissue [see column 3 lines 45-65]. Heifer et al disclose atherosclerosis in all kinds of blood vessels is diagnosed using reflected wavelengths particularly effective in being absorbed by disease states of such vessels, such as plague [see column 5 lines 7-15].

Therefore, one skilled in the art at the time the invention was made would have been motivated to combine Rava et al with Heifer et al by diagnosing a tissue inside a blood vessel; in order to diagnose blood flow for hidden diseases.

Regarding claims 32 and 35, all other limitations are taught as set forth by the above teaching.

Rava et al disclose mid-infrared spectra were measured from 4000 to 700 cmA-1 with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67].

Regarding claim 36, all other limitations are taught as set forth by the above teaching.

Rava et al disclose computer 215 that stores information in a memory as a spectrum which is a graph of intensity vs wavelength [see column 4 lines 55-68]. Rava et al disclose mid-infrared spectra were measured from 4000 to 700 cmA-1 with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67] which means the computer is operable to store any wavelength or wavenumber within the range of 4000 to 700 cmA-1.

Regarding claim 37, all other limitations are taught as set forth by the above teaching.

Rava et al disclose an interferometer [see fig IC].

Regarding claim 38, all other limitations are taught as set forth by the above teaching.

Rava et al disclose a source fiber and a detection fiber having a tip [see column 9 lines 11-45].

Regarding claim 39, all other limitations are taught as set forth by the above teaching.

Rava et al disclose an optical fiber selector 217 [see column 4 lines 35-68].

In addition, Heifer et al disclose Switching mechanism 32 is used to switch the laser to an appropriate fiber, which can be the same switching mechanism as described for illuminating each of the optic fibers 15 with light from source 22 [see column 6 lines 33-45] which is a tunning system.

Regarding claims 44-47, all other limitations are taught as set forth by the above teaching.

Rava et al further disclose irradiating a subsurface portion of atherosclerotic tissue within a vascular lumen to be diagnosed with radiation having a frequency within the infrared range transmitted through a fiber optic cable [see claim 1, Rava et all and further mention the detecting step further comprises collecting the emitted light through the fiber optic cable [see claim 2]. Rava et al disclose the method of spectroscopic diagnosis wherein the coupling step further comprises providing a catheter for insertion into body lumens and the fiber optic cable receives light emitted by the tissue and transmits the emitted light to a spectroscopic analysis system [see claims 4-5].

3. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) in view Helfer et al (US Pat: 5,197,470) as applied to claim 34 above and further in view of Alfano et al (US Pat: 5,293,872).

Regarding claim 40, all other limitations are taught as set forth by the above teaching.

Rava et al don't teach a cooling means for the detector.

Nonetheless, Alfano et al teach a liquid nitrogen cooled indium gallium arsenide photodiode type detector [see column 5 lines 21-23].
Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Rava et al with Alfano by using a liquid cooled type detector; in order to minimize overheating of the detector.

4. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) in view Helfer et al (US Pat: 5,197,470) as applied to claim 34 above and further in view of Corenman et al (US Pat: 4,817,013).

Regarding claim 41, all other limitations are taught as set forth by the above combination.

Rava et al don't teach customized bandwidth and special gain for DC or AC preamps.

Nonetheless, Corenman et al teaches preamp [see 6C]; fig 4A shows AC/DC separation circuit in the amplifiers that receive signal output from three infrared detectors.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Rava et al with Corenman et al r; for the purpose of providing a more efficient system by improving its performance.

5. Claims 33 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (US Pat: 6,697,665) in view Helfer et al (US Pat: 5,197,470) as applied to claim 34 above and further in view of Dumoulin et al (US Pat: 6,129,667).

Regarding claims 33 and 48-49, all other limitations are taught as set forth by the above teaching.

Rava et al don't explicitly mention whether the optical cable 145 is rotatable within the body lumen.

However, it is well known in the art that catheters and endoscope are rotatable within a body lumen such as a blood vessel (emphasis added). Therefore, it is inherent that the fiber optic cable rotates radially within the blood vessel to acquire data at various locations; thus performing 360 degrees spectral analysis (emphasis added).

Nonetheless, Dumoulin et al disclose a fiber optic cable running through an invasive device and the fiber optic cable is rotatable [see claim 3] to acquire data at various locations. Dumoulin et al further disclose creating a tissue map of lumen [see claim 3] which is capable of generating a map of reflectance spectral signals from different locations within the blood vessel.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Rava et al with Dumoulin et al by using the fiber optic cable that rotates within the catheter; in order to have full coverage of the area and to provide an accurate diagnosis of the tissue of interest with the spectral map.

Response to Arguments

6. Applicant's arguments filed 8/15/2011 have been fully considered but they are not persuasive.

Applicant argues that Rava measures signals from the surface while the signals from the pathological conditions are found beneath the surface and further argues that the invention is directed to in vivo detection.

The examiner disagrees because Rava discloses in vivo detection by disclosing catheter 10 is inserted into the artery and the distal end of the catheter is brought into contact with the lesion. Next, a determination is made as to the type of tissue at which each optical fiber 20a-c' is aimed [see column 4 lines 43-49]. Rava et al further disclose in figs 12A and 12B diagnostic measurements within the human body; probe 100 with one or more optical fibers 102 both the incident light to, and the transmitted (reflected) light from, the ATR element 104. A 100% infrared reflector 106 such as gold is placed at the distal surface 108 of the ATR element 104 functions to return the transmitted light back through the same fiber [see column 9 lines 11-25].

Rava et al disclose the probe can either be inserted through a standard endoscope or catheter to sample a hollow organ (or artery) [see column 9 lines 20-32].

It is not clear what Applicant means by the ATR spectroscopy in Rava measures signals from the surface. However, it is well explained above that Rava uses a catheter within the blood vessel to gather signals from the atherosclerotic region.

Applicant argues that the ATR of Rava et al is not used for in vivo detection.

The examiner disagrees because Rava et al also disclose the ATR method is well suited for in vivo detection [see column 14 lines 9-12].

Applicant argues that Rava uses Raman shifts whereas the invention is directed to tissue reflection based mid-IR spectroscopy and further mention that the examiner must be convinced that Rava doesn't teach mid-IR spectroscopy.

The examiner disagrees because as explained in the previous office Rava et al further disclose comparing mid-IR of a normal tissue to atherosclerotic plaque and observe increases in several bands in the atherosclerotic regions [see column 13 lines 46-60]. Rava et al disclose mid-infrared spectra were measured from 4000 to 700 cm^-1 with IR spectrometer [see column 8 lines 31-34 and column 12 lines 56-67]. According to the cited columns, it is clear that Rava discloses mid-IR spectroscopy; therefore, Applicant's arguments are moot. Furthermore, the examiner is not convinced that Rava doesn't disclose mid-IR as mentioned by Applicant.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Thu 8:30 AM to 7:00 PM (Off Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777